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TECH CENTER 1600/2900  
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Girish V. Shah  
SERIAL NO.: 09/251,133  
FILING DATE: 17 February 1999  
TITLE: NEUROENDOCRINE MARKER  
OF PROSTATE CANCER AND  
METHOD FOR PRODUCING SAME

EXAMINER: A. Holleran

AU: 1642

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Assist. Commissioner for Patents  
Washington, D.C. 20231

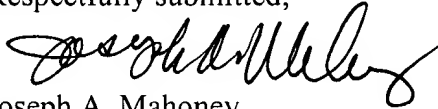
**RESPONSE TO NOTICE TO COMPLY WITH REQUIREMENTS  
FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE AND/OR  
AMINO ACID SEQUENCE LISTING DISCLOSURES**

Dear Sir:

The remarks below are provided in response to the Examiner's communication dated October 4, 2000. Attached hereto is a petition for a two month extension of time under 37 C.F.R. § 1.136. Enclosed is a check in the amount of \$195.00, the necessary fee under 37 C.F.R. § 1.17(a)(1) for said two month extension. Applicant considers this response to have been timely filed pursuant to 37 C.F.R. § 1.7 and § 1.8. Payment of this fee, however, is under protest because Applicant did not receive the Examiner's communication until December 5, 2000. The attorney docketed copy of the Examiner's communication is enclosed herewith. Further, Applicant provided the Examiner a "Notice of Change of Address of Attorney of Record" in the response to the Examiner's communication dated June 20, 2000. Therefore, Applicant's request a refund of the fee provided with this response. The Commissioner is hereby authorized to charge any deficiency in fees associated with this communication, or credit any overpayment to Deposit Account No. 19-3140.

In response to the Examiner's communication dated October 4, 2000 requiring Applicant to furnish nucleotide and/or amino acid sequence listing complying with Patent Office standards in the above-referenced application, Applicant encloses herewith a sequence listing in printed and computer readable form. Applicant confirms that the sequence listing provided herewith does not go beyond the disclosure in the international application as filed. Applicant further encloses a copy of the Notice to Comply as requested in the Examiner's communication.

Respectfully submitted,



Joseph A. Mahoney  
Reg. No. 38,956

December 19, 2000

SONNENSCHN, NATH & ROSENTHAL  
8000 Sears Tower  
233 South Wacker Drive  
Chicago, Illinois 60606-6404  
(312) 876-8192

Docket No. 70009590-0015

Application No.: 09/251,133

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other:

**Applicant Must Provide:**

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

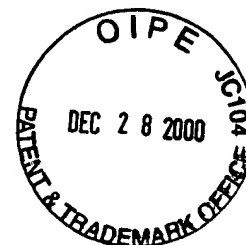
For CRF Submission Help, call (703) 308-4212

PatentIn Software Program Support (SIRA)

Technical Assistance.....703-287-0200

To Purchase PatentIn Software.....703-306-2600

**PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE**



**RAW SEQUENCE LISTING  
ERROR REPORT**

BIOTECHNOLOGY  
SYSTEMS  
BRANCH

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SEP 25 2000

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form: TECH CENTER 1600/2900

Application Serial Number: 09/257,133

Source: 1642

Date Processed by STIC: 9/20/2000



THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.

PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY RECEIVED  
JAN 11 2001  
TECH CENTER 1600/2900  
or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT.  
WITH A NOTICE TO COMPLY

FOR FURTHER INFORMATION, PLEASE TELEPHONE MARK SPENCER,  
703-308-4212.

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER  
VERSION 3.0 PROGRAM ACCESSIBLE THROUGH THE U.S. PATENT AND  
TRADEMARK OFFICE WEBSITE. SEE BELOW:

**Checker Version 3.0**

The Checker Version 3.0 application is a state-of-the-art Windows based software program employing a logical and intuitive user-interface to check whether a sequence listing is in compliance with format and content rules. Checker Version 3.0 works for sequence listings generated for the original version of 37 CFR §§1.821 - 1.825 effective October 1, 1990 (old rules) and the revised version (new rules) effective July 1, 1998 as well as World Intellectual Property Organization (WIPO) Standard ST.25.

Checker Version 3.0 replaces the previous DOS-based version of Checker, and is Y2K-compliant. Checker allows public users to check sequence listings in Computer Readable form (CRF) before submitting them to the United States Patent and Trademark Office (USPTO). Use of Checker prior to filing the sequence listing is expected to result in fewer errored sequence listings, thus saving time and money.

Checker Version 3.0 can be down loaded from the USPTO website at the following address:  
**<http://www.uspto.gov/web/offices/pac/checker>**

## Raw Sequence Listing Error Summary

**ERROR DETECTED SUGGESTED CORRECTION**

SERIAL NUMBER

09/251,123

ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

- 1        Wrapped Nucleics      The number/text at the end of each line "wrapped" down to the next line. This may occur if your file was retrieved in a word processor after creating it. Please adjust your right margin to .3, as this will prevent "wrapping".
- 2        Wrapped Aminoac      The amino acid number/text at the end of each line "wrapped" down to the next line. This may occur if your file was retrieved in a word processor after creating it. Please adjust your right margin to .3, as this will prevent "wrapping".
- 3        Incorrect Line Length      The rules require that a line not exceed 72 characters in length. This includes spaces.
- 4        Misaligned Amino Acid Numbering      The numbering under each 5th amino acid is misaligned. This may be caused by the use of tabs between the numbering. It is recommended to delete any tabs and use spacing between the numbers.
- 5        Non-ASCII      This file was not saved in ASCII (DOS) text, as required by the Sequence Rules. Please ensure your subsequent submission is saved in ASCII text so that it can be processed.
- 6        Variable Length      Sequence(s)        contain n's or Xaa's which represented more than one residue. As per the rules, each n or Xaa can only represent a single residue. Please present the maximum number of each residue having variable length and indicate in the (ix) feature section that some may be missing.
- 7        PatentIn ver. 2.0 "bug"      A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid sequence(s)       . Normally, PatentIn would automatically generate this section from the previously coding nucleic acid sequences. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. This applies primarily to the mandatory <220>-<223> sections for Artificial or Unknown sequences.
- 8        Skipped Sequences (OLD RULES)      Sequence(s)        missing. If intentional, please use the following format for each skipped sequence:  
(2) INFORMATION FOR SEQ ID NO:X:  
(1) SEQUENCE CHARACTERISTICS: (Do not insert any headings under "SEQUENCE CHARACTERISTICS")  
(ix) SEQUENCE DESCRIPTION: SEQ ID NO:X:  
This sequence is intentionally skipped.  
  
Please also adjust the (ix) NUMBER OF SEQUENCES: response to include the skipped sequence(s).
- 9        Skipped Sequences (NEW RULES)      Sequence(s)        missing. If intentional, please use the following format for each skipped sequence.  
<10> sequence id number  
<400> sequence id number  
000
- 10        Use of n's or Xaa's (NEW RULES)      Use of n's and/or Xaa's have been detected in the Sequence Listing. Use of <220> to <223> is MANDATORY if n's or Xaa's are present. In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.
- 11        Use of <213> Organism (NEW RULES)      Sequence(s)        are missing this mandatory field or its response.
- 12        Use of <220> Feature (NEW RULES)      Sequence(s)        are missing the <220> Feature and associated headings. Use of <220> to <223> is MANDATORY if <213> ORGANISM is "Artificial" or "Unknown". Please explain source of genetic material in <220> to <223> section.  
(See "Federal Register," 6/01/98, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of new Rules)
- 13        PatentIn Ver. 2.0 "bug"      Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing). Instead, please use "File Manager" or any other means to copy file to floppy disk.

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H. HOLLERK

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# 8 ALH  
9/27/01

1642

RAW SEQUENCE LISTING  
PATENT APPLICATION: US/09/251,133DATE: 09/20/2000  
TIME: 16:21:27Input Set : A:\Jumedi5  
Output Set: N:\CRF3\09202000\I251133.favDoes Not Comply  
Corrected Diskette Needed

3 <110> APPLICANT: SHAR, Garish V.  
5 <120> TITLE OF INVENTION: NEUROENDOCRINE MARKER OF PROSTATE CANCER AND METHOD FOR  
6 PRODUCING SAME  
8 <130> FILE REFERENCE: 70009590-015  
10 <140> CURRENT APPLICATION NUMBER: 09/251,133  
11 <141> CURRENT FILING DATE: 1999-02-16  
13 <150> PRIOR APPLICATION NUMBER: US 60/074,809  
14 <151> PRIOR FILING DATE: 1998-02-17  
16 <160> NUMBER OF SEQ ID NOS: 12  
18 <170> SOFTWARE: Patencin Ver. 2.0

## ERRORD SEQUENCES

97 <210> SEQ ID NO: 3  
98 <211> LENGTH: 433  
99 <212> TYPE: DNA  
100 <213> ORGANISM: Homo sapien  
102 <400> SEQUENCE: 3  
103 aqaacctgtg tgetgggcta cctgcataata gtgcagagat tcatcgata tccgtgctg 60  
104 gggctcctta gacctgttto acctcaavoa tctgcaagao atccctatac gttttaggca 120  
105 agtagagctga atcttttttt tctttttttt tctgttttct tttttctttt ttctggagct 180  
106 ggggacccgaa cccagagacct tgcgtttgct aggcagagctg tctacacactg agctaaatcg 240  
E--> 107 aaaaacccgac tgcacgtttt ttgtttttta gttaaatctt ggtttggtct attctgtgct 300  
E--> 108 tccctttgtt taaagaaac tctagccggg gtatgtatg tctataatcc cagcagctgg 360  
E--> 109 gaggcaggag gttccagagt tcaagtcggg atggcacaca tgagacatta gctcaaaada 420  
E--> 110 aaaaaaaaaa aaa  
129 <210> SEQ ID NO: 5  
130 <211> LENGTH: 435  
131 <212> TYPE: DNA  
132 <213> ORGANISM: Homo sapien  
134 <400> SEQUENCE: 5  
135 attagaaact gtgtgctggg ctacctgcat atagtgcag agttcactga atctcagctg 60  
136 ctgggggtccc ctagtctctg ttccttcaa cactatgcaag acattcctca agcttatagc 120  
137 caagtaagact gactcctttt tttttttttt tttctgttga atcttctctt tttttctggg 180  
138 ctggggacccg aacccaggag ctgtggcttg ctgggcaagc gctctaccac tgagctaaat 240  
139 tcccaacccc gactgcacag tttttgtttt ttagttaaat tccggtcttc tctatttctg 300  
E--> 140 gttccctttt gtttaaaaga aactgtgccc ggggtatgat atctctataa tccctgcaat 360  
E--> 141 tgggagggcag gaggatccac agttcagtc ggcattggac acatgagacb ttgctcctaa 420  
E--> 142 aaaaaaagaa aaaaa  
183 <210> SEQ ID NO: 9  
184 <211> LENGTH: 103  
185 <212> TYPE: PRT  
186 <213> ORGANISM: Homo sapien  
188 <400> SEQUENCE: 9  
189 Arg Thr Cys Val Leu Gly Tyr Leu His Ile Val Pro Glu Phe Ile Glu  
190 1 5 10 15

invited base (nuclei)  
designator and  
nos. off, as a result  
of above error

359  
numbering off

see next page

## RAW SEQUENCE LISTING

PATENT APPLICATION: US/09/251,133

DATE: 09/20/2000

TIME: 16:21:27

Input Set : A:\Xmcd15

Output Set: H:\CRF3\09202000\I251133.raw

```

182 Ser Gln Leu Leu Gly Leu Leu Ser Pro Val Ser Phe Asn His Met Gln
193          20          25          30
195 Asp Ile Pro Gln Arg Tyr Arg Gln Val Asp Cys Ile Phe Phe Phe Leu
196          35          40          45
198 Phe Phe Ser Phe Ser Phe Phe Phe Phe Ser Glu Leu Gly Thr Glu Pro
E--> 199          50          55          60
201 Arg Thr Leu Arg Leu Leu Gly Lys Arg Ser Thr Thr Glu Leu Asn Pro
E--> 202 665          60 70          65 75          70 80          85
204 Gln Pro Arg Leu His Arg Phe Trp Phe Leu Val Lys Phe Arg Phe Ala
E--> 205          80 85          90          95
207 Leu Phe Arg Val Pro Phe Val
E--> 208          100

```

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misaligned  
amino acid nos.

(see item 4  
on Ena Summary  
sheet)

PT

Please Note:

Use of n and/or Xaa have been detected in the Sequence Listing. Please review the Sequence Listing to ensure that a corresponding explanation is presented in the <220> to <223> fields of each sequence which presents at least one n or Xaa.



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/001-102	02/16/94	SHAH	70009590-001

DAVID G ROSENBAUM  
SONNENSCHN EIN MATH A ROSENTHAL  
3000 PEARLS TOWER  
500 SOUTH WACKER DRIVE  
CHICAGO IL 60606-6404

HM22/1094

EXAMINER

POLLERAN, A

ART UNIT

PAPER NUMBER

642

9

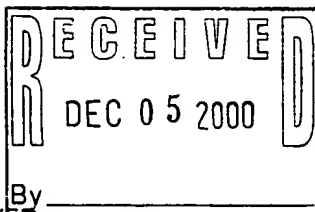
DATE MAILED:

10/04/00



Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



RECEIVED By \_\_\_\_\_ DOCKET  
DOCKETED Response  
DIARIED 11-4-00  
BY [Signature]





**PATENT**

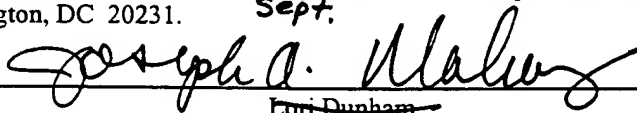
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Girish V. Shah  
SERIAL NO.: 09/251,133 EXAMINER: A. Holleran  
FILING DATE: 17 February 1999 AU: 1642  
TITLE: NEUROENDOCRINE MARKER OF PROSTATE  
CANCER AND METHOD FOR PRODUCING SAME

Assist. Commissioner for Patents  
Washington, D.C. 20231

**CERTIFICATE OF MAILING**

I hereby certify that this document (along with any being referred to attached and/or enclosed) are being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" Mailing Label No. EM 143 604 465 US on this 1 day of ~~July~~ <sup>Sept.</sup>, 2000 in an envelope addressed to the Assist. Commissioner for Patents, Washington, DC 20231.

  
~~Eori Dunham~~

**NOTICE OF CHANGE OF ADDRESS OF  
ATTORNEY OF RECORD**

Dear Sir:

Please correct your records to reflect a new attorney of record as follows:

Joseph A. Mahoney, Reg. No. 38, 956  
SONNENSCHN NATH & ROSENTHAL  
8000 Sears Tower  
233 South Wacker Drive  
Chicago, Illinois 60606-6404  
(312) 876-3119



PATENT

Client Name: No. Ku Medical Center Research, Inc. 70009590-0015  
Title: Anticancer Marker of Prostate Cancer and Method  
Applicant: Girish V. Shah  
Ser.# / Pat.# 09/251,133 Filing Date: 2/16/99

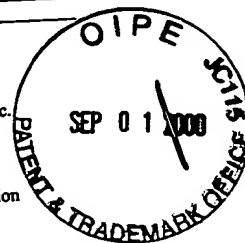
Please acknowledge receipt of:

- ☐ Specification and claims, and  
sheets of drawings, FIG(S).  
☐ Declaration / Oath  
☐ Power of Attorney  
☐ Small Entity Statement  
☐ Check # \_\_\_\_\_  
☐ Patent Assignment Cover Sheet  
☐ Assignment  
☐ Check # \_\_\_\_\_  
☒ Letter - *notice of change of attorney + address*  
☐ Information Disclosure Statement  
☐ Form PTO-1449 & Refer.  
☐ Certification  
☐ Petition  
☐ Check # \_\_\_\_\_

Mailed 9/1/00

- ☐ Preliminary Amendment  
☐ Request for Priority and Pri. Doc.  
☒ Reply to Office Action  
☒ Request for Ext. of Time  
☐ Check # \_\_\_\_\_  
☐ Amendment After Final Rejection  
☐ Request for Ext. of Time  
☐ Check # \_\_\_\_\_  
☐ Corrected Drawings  
☐ Issue Fee Transmittal  
☐ Check # \_\_\_\_\_  
☐ Other *paper copy - see list in 2*  
☒ Maintenance Fee Transmittal Form  
☐ Check # \_\_\_\_\_

☒ Cert. of Mailing  
Express Mail No. EM143604465  
By Barbara Balsamo



EM143604465US